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PATENT
Attorney Docket No.: 015280-352100US
Client Ref. No.: E-143-1998/0-US-04

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On

TOWNSEND and TOWNSEND and CREW LLP

By:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PAVLAKIS and NAPPI

Application No.: 09/673,716

Filed: February 26, 2001

For: NOVEL POST-
TRANSCRIPTIONAL REGULATORY
ELEMENTS AND USES THEREOF

Customer No.: 20350

Confirmation No. 4088

Examiner: Winkler, Ulrike

Technology Center/Art Unit: 1648

Declaration of George N. Pavlakis and
Filomena Nappi pursuant to 37 C. F. R.
§1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, George N. Pavlakis and Filomena Nappi, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. §1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of our own knowledge are true and statements made on information or belief are believed to be true. Exhibit I is attached hereto and are incorporated herein by reference.

Appl. No. 09/673,716

PATENT

Declaration under 37 C.F.R. §1.131

Reply to Office Action of October 21, 2003

2. At the time this invention was first conceived, we were employees of the Basic Research Program, Advanced Biosciences Laboratory, a contractor of the National Cancer Institute, located in Frederick, Maryland. All activities described in this Declaration took place in the United States of America.

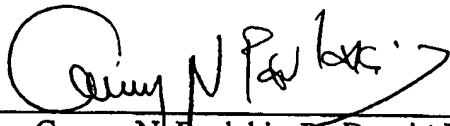
3. In accordance with 37 C.F.R. §1.131, we state that we completed the claimed invention in the United States prior to October 20, 1997, which is the earliest entry date for GenBank Accession Nos. C80177 and C80740.

4. Attached to this Declaration is Exhibit I, the dates on which have been redacted. All redacted dates are prior to October 20, 1997.

5. Conception of the present invention as well as its reduction to practice are evidenced by Exhibit I, which is a copy of a printout containing the polynucleotide sequences of SEQ ID NO:1 (termed "FNC3B") and SEQ ID NO:4 (termed "PRE7" or "IAP") of the present application, as well as sequence alignment results between SEQ ID NO:1 or FNC3B with other known sequences.

6. In light of the foregoing, it is established that Declarants had in their possession the claimed subject matter of the present invention prior to October 20, 1997.

7. Declarants have nothing further to say.

Dated: March 21, 2004By: 
George N. Pavlakis, Ph.D., M.P.

Dated: _____

By: _____
Filomena Nappi, Ph.D.Attachments (Exhibit I: redacted copy of sequences and alignment results)
60135517 V1

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

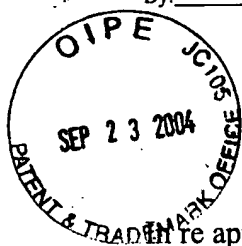
PATENT
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2. At the time this invention was first conceived, we were employees of the Basic Research Program, Advanced Biosciences Laboratory, a contractor of the National Cancer Institute, located in Frederick, Maryland. All activities described in this Declaration took place in the United States of America.

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6. In light of the foregoing, it is established that Declarants had in their possession the claimed subject matter of the present invention prior to October 20, 1997.

7. Declarants have nothing further to say.

Dated: _____

By: _____
George N. Pavlakis, Ph.D.

Dated: 03/09/2004

By: Filomena Nappi
Filomena Nappi, Ph.D.

Attachments (Exhibit I: redacted copy of sequences and alignment results)
60135517 V1

I enclose a file containing the nucleotide sequence of the PRE7(IAP) as is the provisional name we have selected for this element, which is involved in posttranscriptional regulation.

We have identified elements that have homology to PRE7(IAP) from the databases. The alignment of these elements is provided. None of these elements has been characterized functionally. Our work is the first that identified these sequences as potential posttranscriptional control elements. At present, PRE7(IAP) is the only one for which we have functional data.

In the aligned sequences, our functional PRE7(IAP) is called FNC3B. Only the "core" 231 nt element containing the functional element is shown.

FNC3B

TGTTGGGCTGCGAGGCTAAGCACTGCACAGAGGATAGCTTGCTGTTGGCATCCTGTGGAAGG
CACGTCTGATTGCATGAAGGTTCAAGTGTCTAGTTCCCTTCCCCCAGGAAAAACGACACG
GGAGCTGGCCAAGACCTCTCTGGGTGATGAGCCTAAGGGATGGTTTTGTGTAGGGCCCCT
ATGCTTGCACACTGGGGATCAGACCTCTACCTTCACCCATGAGGCTTGCTT

PRE7 (IAP)

CTTTCGCCATGGTAGCATAGGCTTTTGCTGCAGTGGAGGCGGGACAATCTCCTCAGATTC
GGTTTGCCGCTCTAAAAGAAATTATGCTGCGTTATGCCGTGGGGTGCGAGGCTAAGCACT
GCACAGAGGATAGCTTGCTGTTGGCATCCTGTGGAAGGCACGTCTGATTGCATGAAGGTT
CAGTGTCTAGTTCCCTTCCCCCAGGAAAAACGACACGGGAGCTGGCCAAGACCTCTCTG
GGTGATGAGCCTAAGGGATGGTTTTGTGTAGGGCCCCTATGCTTGCACACTGGGGATCAG
ACCTCTACCTTCACCCATGAGGCTTGCTTGCAGCAATTAAGATCTGGCCATAGGTTAATT
AACATCCTGGCCTTTTGATGCACCTGCCACAAG

the underlined sequences correspond to the aligned fragment
FNC3B

The alignment of the sequences found in the database
follows:

(4)

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FNC3B.seq      Begin:99 End:329
GB:X57268      Begin:1599 End:1841
GB:M10134      Begin:7308 End:7538
GB:X01172      Begin:2423 End:2668
GB:M12515      Begin:188 End:418
AE000664.seq   Begin:118019 End:118264
GB:M18252      Begin:3418 End:3662
GB:M18251      Begin:1630 End:1874
GB:S74315      Begin:3824 End:4068
GB:M10062      Begin:2711 End:2955
GB:E00593      Begin:2711 End:2955
E01116.gb_pat  Begin:2711 End:2955
GB:E00594      Begin:3537 End:3781
E01117.gb_pat  Begin:4388 End:4632
GB:X54077      Begin:2200 End:2444
GB:X04120      Begin:4477 End:4721
GB:X97915      Begin:839 End:1083
GB:M17551      Begin:6474 End:6721
GB:U58494      Begin:6192 End:6439
U70139.gcq     Begin:4321 End:4565

```

!!NA MULTIPLE ALIGNMENT 1.0
FileUp of: @CTE-setClg.list

Symbol comparison table: GenRunData:pileupdna.cmp CompCheck: 6876

GapWeight: 2
GapLengthWeight: 1

CTE-setClg.msf MSF: 251 Type: N 10:03 Check: 7329 ..

Name: FNC3B	Len: 251	Check: 6699	Weight: 1.00
Name: X57268	Len: 251	Check: 7888	Weight: 1.00
Name: M10134	Len: 251	Check: 8724	Weight: 1.00
Name: X01172	Len: 251	Check: 3612	Weight: 1.00
Name: M12515	Len: 251	Check: 112	Weight: 1.00
Name: AE000664	Len: 251	Check: 4675	Weight: 1.00
Name: M18252	Len: 251	Check: 1995	Weight: 1.00
Name: M18251	Len: 251	Check: 2423	Weight: 1.00
Name: S74315	Len: 251	Check: 1833	Weight: 1.00
Name: M10062	Len: 251	Check: 1751	Weight: 1.00
Name: E00593	Len: 251	Check: 1751	Weight: 1.00
Name: E01116	Len: 251	Check: 1751	Weight: 1.00
Name: E00594	Len: 251	Check: 1811	Weight: 1.00
Name: E01117	Len: 251	Check: 1811	Weight: 1.00
Name: X54077	Len: 251	Check: 2537	Weight: 1.00
Name: X04120	Len: 251	Check: 2537	Weight: 1.00
Name: X97915	Len: 251	Check: 3213	Weight: 1.00
Name: M17551	Len: 251	Check: 5139	Weight: 1.00
Name: U58494	Len: 251	Check: 5139	Weight: 1.00
Name: U70139	Len: 251	Check: 1928	Weight: 1.00

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1
FNC3B GTGGGGTTCG AGGCTAAGC. ACTGCACAGA GGATAGCTT. ...GCTGT.T GG.CATCCTG T.GGAAGGCA CGT
X57268 GAGAGTTGTA AGACTAAGT. ACTGCACAGA GATTAGTCTA GAAGCTGT.T GGACAGTCTC T.GAGAGGCA TGT
M10134 AGGAGTTGCA AGGCTAAGC. ACTGCACAGG AGAGG.TCTG CGG..TATAA CGACTTTCTC CTGGGAGATA AGT
X01172 GAGAGTTGCA CGGCTAAGC. ACTGCAGTAG AAGGGCTCTG CGGCACATAT GAGCCTATTTC TAGGGAGACA TGT
M12515 GAGAGTCG.A AGGCTAAGCA ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTTC TAGGGAGACA TGT
AE000664 GAGAGTTGCA CGGCTAAGC. ACTGCAGTAG AAAGGCTCTG CGGCATATAT GAGCCTATTTC TAGGGAGACA TGT
M18252 GAGAGTTGCA CGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTTC TAGGGAGACA TGT
M18251 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTTC TAGGGAGACA TGT
S74315 GAGAGTTGCA CGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTTC TAGGGAGACA TGT
M10062 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTTC TAGGGAAACA TGT
E00593 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTTC TAGGGAAACA TGT

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E01116 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGAAACA TGTC
E00594 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGAGACA TGTC
E01117 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGAGACA TGTC
X54077 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGAGACA TGTC
X04120 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGAGACA TGTC
X97915 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GTGCCTATTC TAGGGGGACA TGTC
M17551 GAGAGTTGCA CGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGAGACA TGTC
U58494 GAGAGTTGCA CGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGAGACA TGTC
U70139 GAGAGTTGCA AGGCTAAGC. ACTGCAATGG AAAGGCTCTG CGGCATATAT GAGCCTATTC TAGGGNGACA TGTC

101

FNC3B AGTTCCTTC .CCCCAGGAA AAACGACACG GGAGCTGGCC AAGACC.TCT CTGGGTGA..TGAGC CT..
X57268 AGGGGCTTT .CCCCAGAAA AAAGGGCACA GGAGCAGGTC AGGGTT.ACT CTGGGTAAAG ATCTGTGGGC CT..
M10134 GATCTCCTT. .CCCCAGAAA AAAAGACATC GGA.CTGGTC AGGACTTCCT CTGGGGATAA G.....ACC CTG..
X01172 AGTGTCTTC TCCCCAGGAA AAACGGCACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTGAGC CT..
M12515 AGTTCCTTC .CCCCAGGCA AAACGACACG GGA.CAGGTC AGGGTT.GCT CTGGGTAAAA .CCTGTAAGC CT..
AE000664 AGTGTCTTC TCTCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTGAGC CT..
M18252 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTGAGC CT..
M18251 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GTT CTGGGTAAAA GCCTGTAAGC CT..
S74315 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTAAGC CT..
M10062 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTAAGC CT..
E00593 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTAAGC CT..
E01116 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTAAGC CT..
E00594 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTAAGC CT..
E01117 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTAAGC CT..
X54077 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTGAGC CT..
X04120 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTGAGC CT..
X97915 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTGAGC CT..
M17551 AGTTGCCCT. TCCCCAGGCA AAACGACAC. GGAGCAGGTC AGGGTTGGCT CTGGGTAAAA GCCTGTGAGC CTC
U58494 AGTTGCCCT. TCCCCAGGCA AAACGACAC. GGAGCAGGTC AGGGTTGGCT CTGGGTAAAA GCCTGTGAGC CTC
U70139 AGTTCCTTC .CCCCAGGCA AAACGACACG GGAGCAGGTC AGGGTT.GCT CTGGGTAAAA GCCTGTAAGC CT..

201

FNC3B TG.CTTGCAC ACTGGGGATC AGACCTCTAC CTTCACCCAT GAGGCTTGCT T
X57268 AC.ATGACAC ACTGGGGATC AGACCTCTAC CTCTACCCAC GGAGCTTGCT T
M10134 T...TTGCAC A.TGGGGATT TGACCTCTAT CTCCACTC.C AAAGTTGTGG G
X01172 T.ACCTGCAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
M12515 TTACTACAC ACTGGG... TGACCTCTAT CT.CACTCTC ATCAATATGG T
AE000664 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAGTTGGG T
M18252 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
M18251 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
S74315 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
M10062 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
E00593 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
E01116 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
E00594 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
E01117 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
X54077 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
X04120 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
X97915 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
M17551 TGACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
U58494 TGACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G
U70139 T.ACCTACAC ACTGGGGATT TGACCTCTAT CTCCACTCTC ATTAATATGG G

251

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PRETTY of: CTE-setClg.msf(*)

10:04 ..